REMARKS

The Examiner has acknowledged Applicant's election with traversal of Group I (claims 1 – 3) and the species inositol-1, 4 5-triphosphate 3-kinase (ITPKC). The Examiner has considered Applicant's argument that the claims are based on the detection of an interaction of the kinase encoded by inositol-1, 4 5-triphosphate 3-kinase and a test agent, and whether or not that interaction occurs using an isolated enzyme or enzyme expressed in a cell would not impact the search burden on the examiner, because art teaching either species would anticipate the claim. Further, the assays do not utilize different products and do not require separate searches. Applicants also argue that the Examiner did not provided any rationale as to why the two alleged species (isolated vs. cell expressed) were patentably distinct so as to necessitate further restriction. The Examiner has found Applicant's arguments to be partially persuasive. The Examiner agrees that art teaching either an isolated enzyme or an enzyme expressed in the cell would anticipate or obviate the claims. Thus, the Examiner agrees that claims 1 – 3 will be examined insomuch as they pertain to a method of identifying an agent that modulates ITPKC.

The Examiner has accepted the drawings filed on February 18, 2004.

Claims 1 - 12 are currently pending in the application. Claims 1 - 3 are amended. Claims 4 - 12 have been withdrawn. The amendments find support in the specification. Specifically, the amendments to detecting the presence or absence of an apoptotic signal are supported in Examples 6 and 7 of the instant specification, which list various assays one would use to determine the apoptotic signals listed. New claims 13 and 14 have been added. Support for these claims can be found in the claims and in the specification, particularly at paragraph [0361] of the published application which teaches specifically that inhibition can preferably be 75%. No new matter is added.

Priority

The Examiner acknowledges Applicant's claim for foreign priority based on an application filed in the United Kingdom on 23 January 2003. However, the Examiner notes that Applicant has not filed a certified copy of the 0301566.6 application. Applicant has requested a

certified copy of the 0301566.6 application as required by 35 U.S.C. 119(b), and will submit the certified copy as soon as it is received.

Objections

The Examiner objects to the specification because it contains embedded hyperlink and/or other form of browser executable code. Applicants have made the appropriate changes to the specification and respectfully request withdrawal of the objection.

The Examiner has objected to reference to the proteins of Table 1B by GenBank number. The Examiner argues that because a GenBank number can change, it is improper to refer to proteins by GenBank number, and requests SEQ ID NOs as identifiers. Applicants argue that the sequence rules pertain to the disclosure of sequences, not protein names. Further, GenBank changes can be tracked and related to the filing date of the application, allowing full written description of the protein referenced by the GenBank number. Applicants respectfully request withdrawal of the objection.

The Examiner has objected to claims 1 – 3 because the claims encompass non-elected subject matter. Applicants have made appropriate correction to the claims to recite the elected species, and respectfully request withdrawal of the rejection.

Claims Rejected under 35 USC §112, second paragraph

The Examiner has rejected claims 1 – 3 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended the claims to recite the elected species, inositol-1, 4 5-triphosphate 3-kinase C. Applicants have removed reference to the Table in the claims. As such, the claims are no longer indefinite, and applicants respectfully request withdrawal of the rejection.

Applicants respectfully request withdrawal of the 35 U.S.C. §112 second paragraph rejection and reconsideration of the instant claims.

Claims Rejected under 35 USC §112, first paragraph

The Examiner has rejected claims 1 – 3 under 35 U.S.C. 112 first paragraph, because the specification, while being enabling for a method of identifying an agent that modulates **the full length of the protein** encoded by the gene for inositol-1, 4 5-triphosphate 3-kinase C (ITPKC), does not reasonably provide enablement for a method of identifying an agent that modulates the protein fragment as shown in SEQ ID NO: 226. Applicants respectfully traverse the rejection.

Applicants direct the Examiner to the Response to Restriction requirement mailed on December 20, 2005. The Restriction Requirement set forth by the Examiner included a requirement that Applicants elect a single protein encoded by a gene presented in Table 1B. In response to the Restriction, Applicants elected inositol-1, 4 5-triphosphate 3-kinase C (ITPKC), for prosecution on the merits. Thus, the elected species is ITPKC, not SEQ ID NO: 226.

The Examiner argues that the claims are not enabled because undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. Applicants disagree. The Examiner admits that the claims are enabled for a method of identifying an agent that modulates the full length protein, and that the prior art teaches the amino acid sequence of ITPKC. Applicants need not re-teach the sequence of ITPKC known in the art in order to enable the claimed invention. A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The claims recite a screening assay that utilizes the interaction between ITPKC and a test agent. The specification provides detailed description of how to perform the methods of the invention. For example, the specification provides a description of assays which are suitable for identifying modulators of GPCR and protein kinases ([0360] of the published application). The specification teaches assays that can be used, candidate agents that can be tested (see, for example [0373] [0374]), how to detect an interaction ([0379] [0380]), and how to identify a modulator of apoptosis-activity of ITPKC [0381]. Further, the specification teaches polypeptide binding assays that can be performed with any polypeptide of the invention [0382]. The

teachings of the specification provide one of skill in the art with guidance to perform the method using ITPKC without resorting to undue experimentation.

In view of the above, Applicants respectfully request withdrawal of the 35 U.S.C. §112 first paragraph rejection and reconsideration of the instant claims.

Claims Rejected under 35 USC §102 (b)

Claims 1 –3 have been rejected under 35 USC §102 (b) as being anticipated by Dewaste et al. (Biochem J 2000). The Examiner argues that regarding claims 1 – 3 that the Dewaste reference teaches a method of expressing ITPKC in *E.coli* and COS-7 cells, treating with Ca2+, and measuring kinase activity. Applicants respectfully traverse the rejection.

The claims, as amended, recite a method of identifying an agent that modulates the function of ITPKC and determining whether the test agent interacts with ITPKC by detecting the presence or absence of a set of apoptotic signals, including caspase activation, DNA fragmentation, cell death, lack of cell proliferation, amount of G1 DNA, change in mitochondrial membrane potential, and externalization of phosphatidylserine. The specification teaches specific methods to detect the apoptotic signal, and thereby determine whether the test agent modulates the function of ITPKC. Examples 6 and 7, for example, teach specific assays that can be used to determine each of the above mentioned apoptotic signals.

The teachings of Dewaste et al. encompass a method of expressing ITPKC in *E.coli* and COS-7 cells, treating with Ca2+, and measuring the kinase activity. As such, the teachings of Dewaste et al. do not address all of the limitations set forth in claim 1. The cited art does not teach detecting the presence or absence of an apoptotic signal, specifically those signals recited in claim 1. The cited art does not teach the test agents as set forth in new claim 13, but rather teaches only Ca2+. The cited art does not teach detecting a 75% change in a signal generated from the interaction of the agent with ITPKC, as taught in new claim 14. The Examiner notes that the art teaches determining phosphotransferase activity; however the reference only teaches determining a 50% change, and does not teach or suggest a 75% change as a cutoff for determination of a change in activity. Thus, Applicants respectfully request withdrawal of the 35 U.S.C. §102 (b) rejection and reconsideration of the instant claims.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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